K112485

DEC - 6 2011

510(k) SUMMARY

Electronic Waveform Lab Inc.'s H-Wave® Electrical Stimulator (model H4)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Electronic Waveform Lab, Inc.
5702 Bolsa Ave.
Huntington Beach, CA 92649

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Contact Person: Ryan P. Heaney, President

Date Prepared: October 4, 2011

Name of Device

H-Wave® (model H4)

Common or Usual Name/Classification Name

Transcutaneous Electrical Nerve Stimulator for Pain Relief
21 C.F.R. § 882.5890 (Product Code GZJ)

Predicate Devices

Model P, Electronic Waveform Lab, Inc. (K813601)
Model H-Wave® H4, Electronic Waveform Lab, Inc. (K103738)
Model HMS DHR-3, Home Medical Services, Inc. (K021496)

Intended Use / Indications for Use

The H-Wave® H4 is indicated for the treatment of chronic pain, acute pain, post-surgical pain, and temporary pain.

Technological Characteristics

The H-Wave® model H4 consists of a portable battery operated electrical stimulation device with two channels, two sets of lead wires, three packages of self-adhesive electrodes, and a battery charger. Each channel has a pair of buttons to select the desired frequency and a dial to control the intensity of the signal. The stimulator also is supplied with an output jack for each channel, a charging jack, timer buttons, and an LCD display. The device creates therapeutic stimulation at frequencies of 1–70 Hz depending on the physician instructions and patient settings.

Performance Data

The H-Wave conforms to the following recognized consensus standards:

- IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.
- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 subclause 56.3(c).
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (2001).

Substantial Equivalence

A chart comparing the similarities and differences between the H-Wave® H4 and its predicate devices is included below:

	EWL H-Wave H4 (Proposed Device)	**EWL P-Tens (K813601)**	**EWL H-Wave H4 (K103738)**	**Home Medical Services HMS-DHR 3 (K021496)**
Frequency	1–70 Hz	14–66 Hz	1–70 Hz	2–60 Hz (+/- 20%)
Power Source	Ni-MH rechargeable battery (7.2 V; 1800 mA/h)		Ni-MH rechargeable battery (7.2 V; 1800 mA/h)	Ni-MH rechargable battery (3.6V)
Line Current Isolation	Yes (battery operated)	Yes (battery operated)	Yes (battery operated)	Yes (battery operated)
Patient Leakage Current				
Normal condition	0	0	0	0
Single fault condition	0	0	0	0
Average DC current through electrodes when device is on but no pulses are being applied (μA)	0	0	0	0
Number of output modes	N/A	N/A	N/A	N/A
Number of output channels	2	1	2	3
Synchronous or alternating	Alternating	Alternating	Alternating	Alternating
Method of Channel Isolation	Galvanic	Galvanic	Galvanic	Galvanic
Regulated Current or Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage
Software/firmware/ microprocessor	Yes	No	Yes	Yes
Automatic Overload Trip	No	No	No	No

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	EWL H-Wave H4 (Proposed Device)	EWL P-Tens (K813601)	EWL H-Wave H4 (K103738)	Home Medical Services HMS-DHR 3 (K021496)
Automatic No-Load Trip	Yes	No	Yes	No
Automatic Shut Off	No	No	No	Yes
Patient Override Control	Yes	Yes	Yes	Yes
Indicator Display				
On/Off Status	Yes	Yes	Yes	Yes
Low Battery	Yes	Yes	Yes	No
Voltage/Current Level	Yes	Yes	Yes	Yes
Timer Range (minutes)	0–60	N/A	0-60	10–60 (5 min intervals)
Compliance with Voluntary Standards	Yes IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 subclause 56.3(c) IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -	N/A	Yes IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 subclause 56.3(c) IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -	Unknown

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	EWL H-Wave H4 (Proposed Device)	EWL P-Tens (K813601)	EWL H-Wave H4 (K103738)	Home Medical Services HMS-DHR 3 (K021496)
	Requirements and Tests (2001)		Requirements and Tests (2001)	
Compliance with 21CFR Part 898	Yes	Yes	Yes	Yes
Weight	1.6 lb	2lb	1.6 lb	1lb
Dimensions	7" x 4.5" x 1.5"	6"x2.34"x6"	7" x 4.5" x 1.5"	6.625"Lx4"W x1.75"H
Housing materials and constructions	ABS plastic housing fastened with screws	ABS plastic housing fastened with screws	ABS plastic housing fastened with screws	Molded ABS

The H-Wave® H4 has the same intended uses and substantially similar output parameters as the predicate devices. Specifically, the H-Wave H4 has the same intended uses and substantially similar output parameters as other legally marketed electrical nerve stimulators: the EWL model P (K813601) and the Home Medical Services, Inc. HMS DHR-3 (K021496). In addition, as the H-Wave H4 is technologically identical to the predicate H-Wave® H4 device, the technological characteristics and principles of operation of the H-Wave H4 do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 6 2011

Electronic Waveform Lab, Inc.
c/o Mr. Ryan P. Heaney
President
5702 Bolsa Ave.
Huntington Beach, CA 92649

Re: K112485
Trade/Device Name: H-Wave® H4
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZJ
Dated: October 4, 2011
Received: October 4, 2011

Dear Mr. Heaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112485

Device Name: H-Wave® H4

Indications for Use:

The H-Wave® H4 is indicated for the treatment of chronic pain, acute pain, post-surgical pain, and temporary pain.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112485